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(58) Field of Search

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INT CL⁶ F16L 37/28
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(54) Abstract Title

Medical fluid line arrangement

(57) A medical fluid line arrangement includes coupling elements 3,4 engageable in a coupled configuration, the respective coupling elements being decoupled upon a predetermined separating force acting to separate the coupling elements. The coupling elements 3,4 are fitted to respective cut ends of a cut tube 1. Fluid is permitted to flow through the engaged coupling elements; the coupling elements typically seal the relevant end of the respective fluid line element upon decoupling. The level of the force required to effect decoupling may be varied.

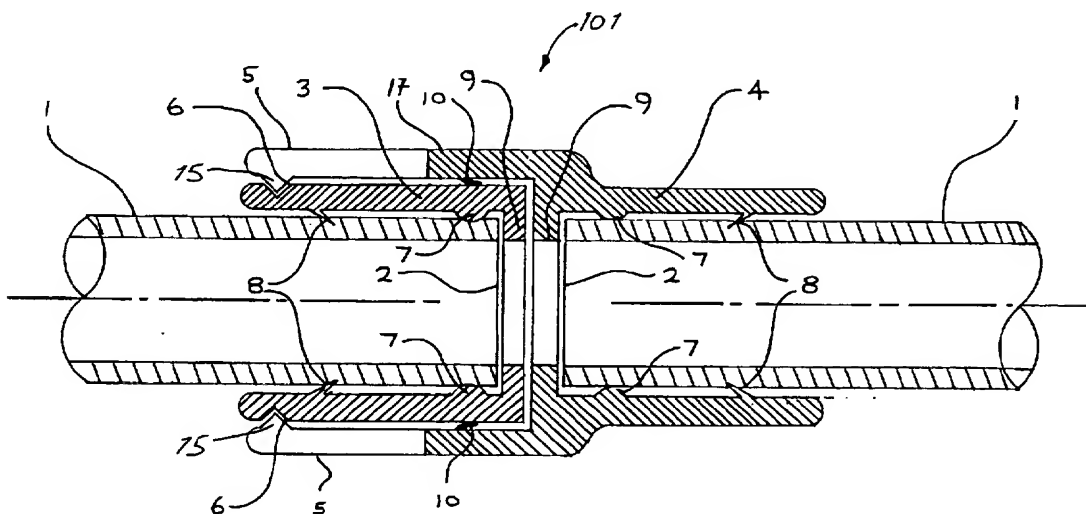


Fig. 1

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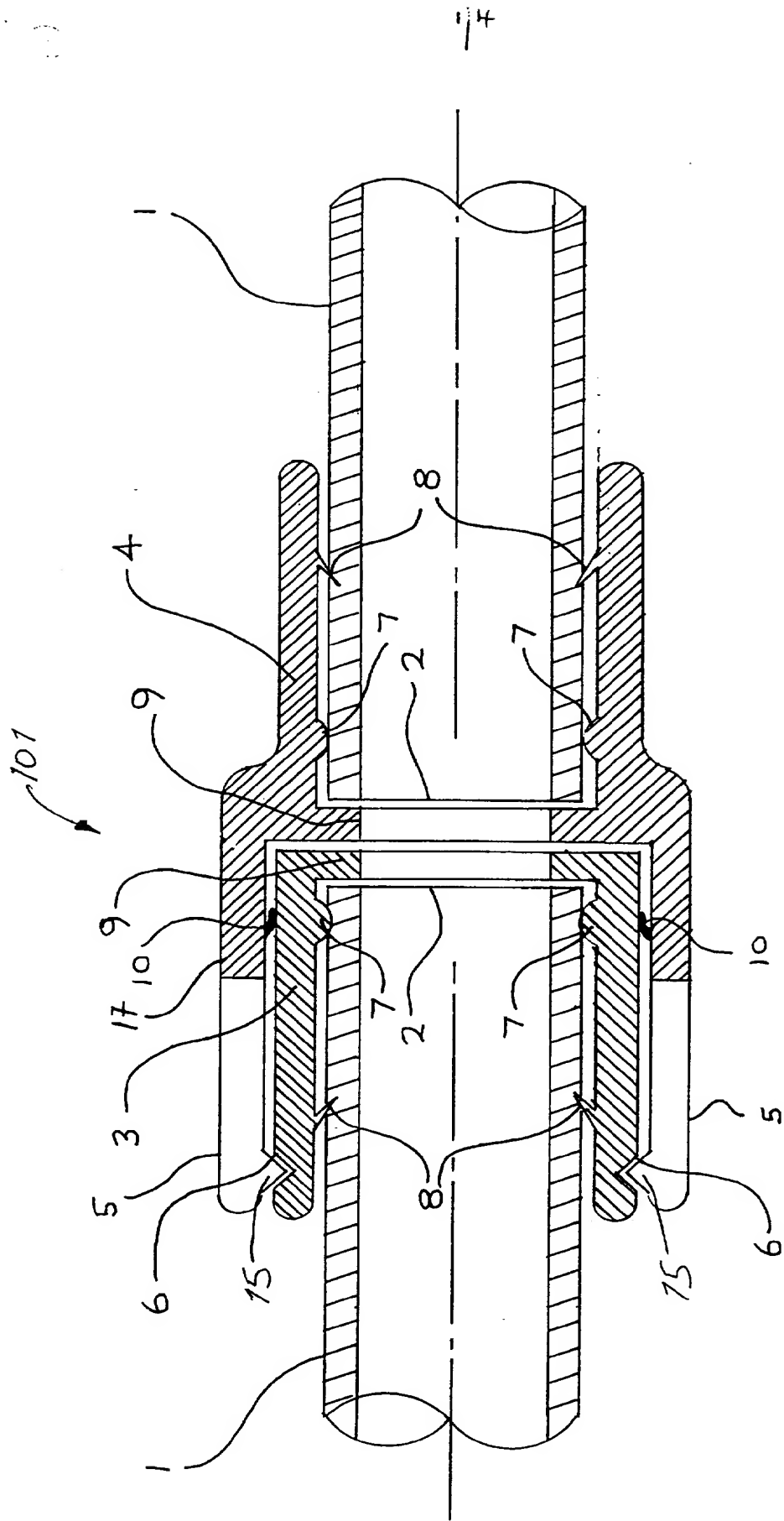


Fig. 1

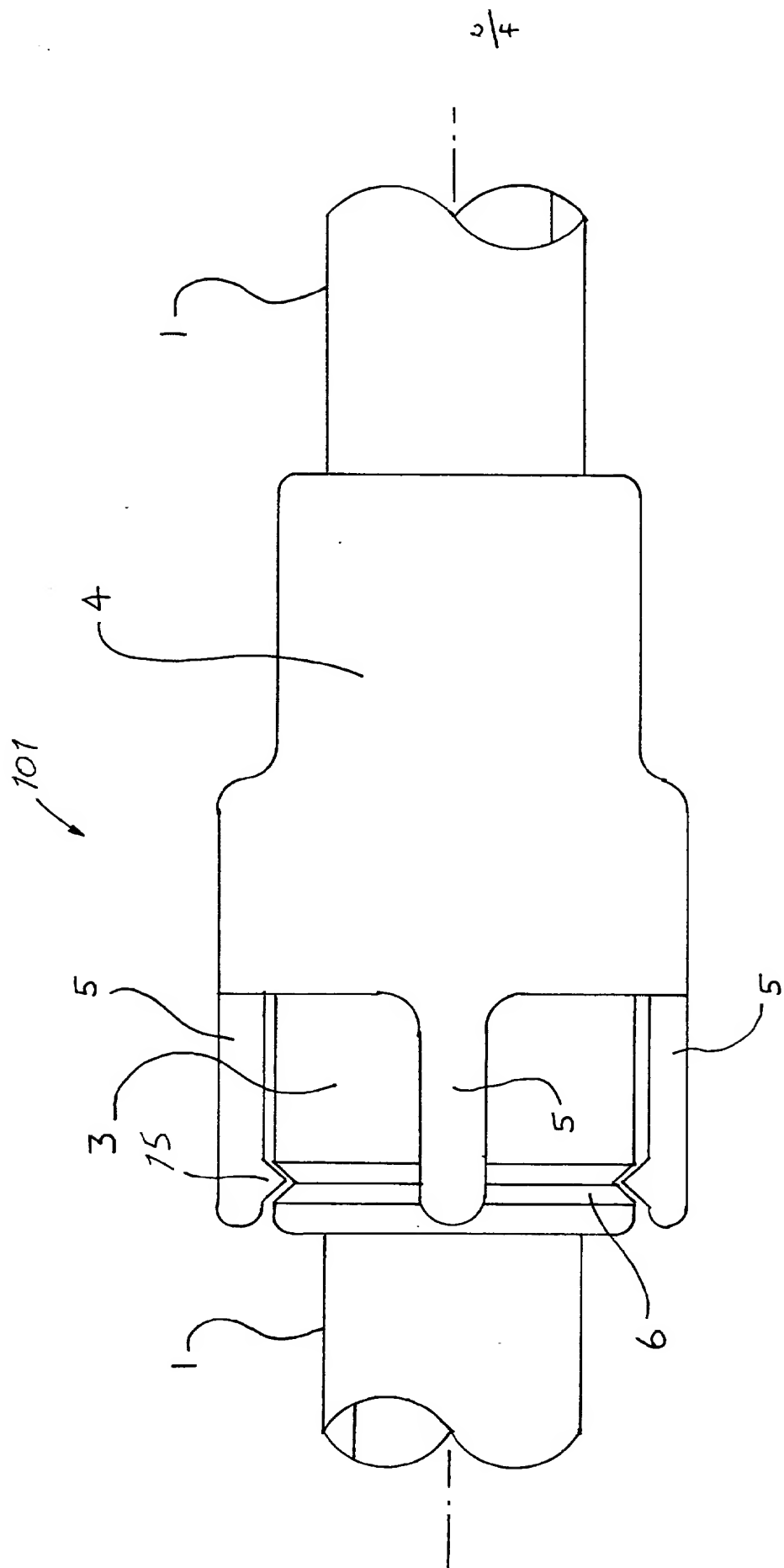


Fig 2

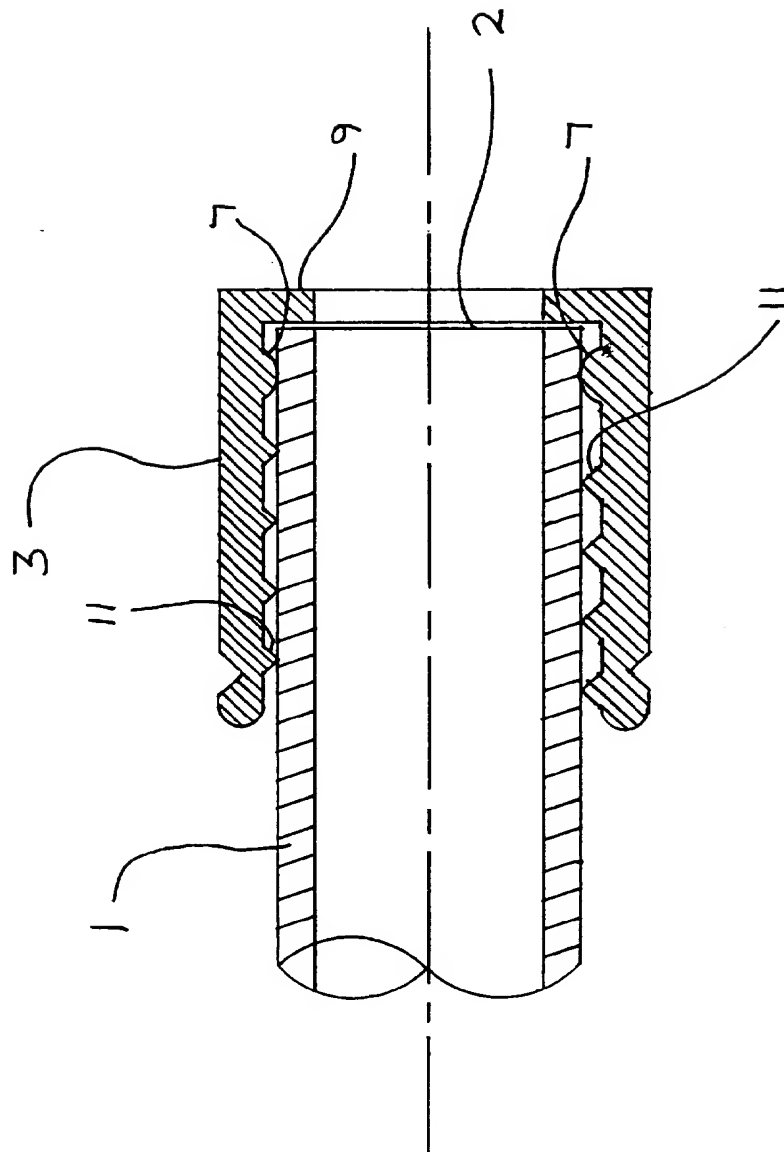


Fig 3

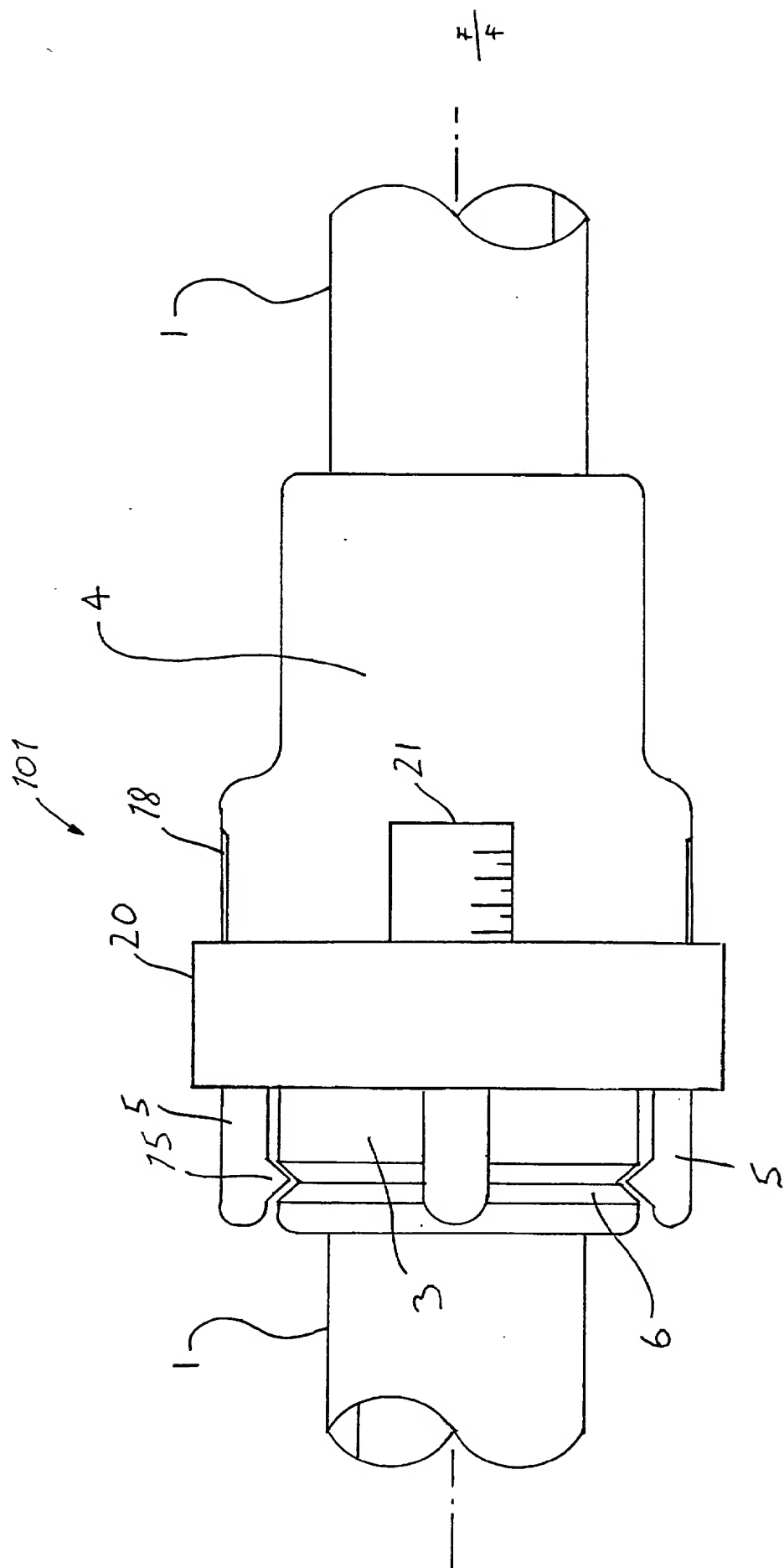


Fig 4

Medical Fluid line Arrangement

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The present invention relates to a medical fluid line arrangement.

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In medical environments, fluid lines such as tubes of different shapes and sizes are commonly used for different functions, for example, for drainage of the gall bladder. A tube of the type commonly used for drainage of the gall bladder has one open end and one closed end with a drainage hole. The closed end may be formed into a loop to form a method of securing the tube within the organ in the body to be drained. The open end of the drainage tube is connected to a collecting bag, or the like, outside the body. Sutures and adhesive plasters are also used to reinforce the securing of the fixed drainage tube to the patients body. A common problem associated with the use of such tubes is that they can be pulled out accidentally for example by a patient treading on the drainage bag.

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When a fluid line is inadvertently dislodged from its position inside the body it has to be re-installed. This is uncomfortable and inconvenient for the patient and time consuming for the medical staff. Reinstallation usually requires a qualified doctor to reposition the fluid line and sometimes requires the use of diagnostic aids, for example ultrasound or CT scans. This makes reinstallation of a drainage tube a costly and largely unnecessary procedure.

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Improved medical fluid line arrangement has now been achieved.

According to a first aspect, the invention provides a medical fluid line arrangement including a coupling comprising:

- 5 i) a first coupling element;
- ii) a second coupling element configured for releaseable engagement with the first coupling element in a coupled configuration permitting
10 fluid communication through the coupling; and,
- iii) engagement means acting to secure the coupling elements in the coupled configuration, the
15 respective engagement means being decoupled upon a predetermined separating force acting to
 separate the coupling elements.

20 The coupling elements are secured to respective upstream and downstream fluid line elements. The separating force for separating the coupling elements from the coupled configuration is preferably substantially less than the force required to disassemble the coupling elements from the respective fluid line element.

25 Typically one fluid line element (desirably the upstream element) is fixed in position in the body of a patient. The separating force required to effect decoupling of the coupling elements from the coupled configuration is preferably less than the force required to dislodge the
30 respective fluid line element from fixation in (or to) the patient's body.

35 Desirably the separating force for the coupling elements is substantially in the range 5N to 25N (more preferably substantially in the range 5N to 15N).

According to a second aspect, the invention provides medical apparatus comprising:

- 5 i) an upstream medical arrangement to be fixed internally of a patient, the upstream arrangement comprising an upstream fluid line element;
- 10 ii) a downstream medical arrangement comprising a downstream fluid line element; and,
- 15 iii) a coupling connecting respective fluid lines of the upstream and downstream medical arrangements, the coupling including first and second coupling elements configured for
20 releaseable engagement with one another in a coupled configuration permitting fluid communication through the coupling elements, and engagement means acting to secure the coupling elements in the coupled configuration, the
25 respective engagement means being decoupled upon a predetermined separating force acting to separate the coupling elements.
- 30 The level of the separating force may be fixed or variable. Preferably the separating force can be varied manually to suit varying degrees of fixity of the upstream
35 fluid line element to the patient.
- The first and second coupling elements preferably comprise respective male and female coupling elements arranged to matingly engage in the coupled configuration. Desirably the first and second coupling elements include respective axial openings arranged to be co-aligned in the coupled configuration, permitting fluid communication through the

coupling.

The male connector element is preferably provided for the upstream fluid line element

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The engagement means for the connector elements preferably include respective complementary engagement formations engageable with one another in the coupled configuration of the connector elements. Desirably, an engagement formation of one or other (or both) of the coupling elements is resiliently displaceable from engagement with the respective complementary formation, permitting decoupling of the coupling elements.

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At least one of the engagement formations may be provided on a resiliently displaceable element such as an arm, preferably comprising the female coupling. Desirably at least two such displaceable elements or arms are provided. In one embodiment a male coupling element is received within a female coupling element, which female element beneficially includes preferably comprises a collar portion and at least one arm extending from the collar portion in the axial direction. A plurality of radially spaced arms are preferably provided extending in the axial direction of the coupling, the arms carrying respective engagement formations for engaging one or more complementary engagement formations provided for the male coupling element. The arm or arms preferably have free ends capable of displacement relative to the coupling axis.

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The engagement formations may comprise respective projections, ribs, ridges or the like arranged to engage with respective complementary depressions, recesses, grooves, slots or the like. An engagement formation for

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at least one of the coupling elements preferably runs circumferentially about the respective coupling element, desirably comprising a continuously running circumferential formation extending through substantially 360 degrees.

At least one of the engagement formations preferably comprises a detent surface inclined to the axial direction of the coupling. The inclined detent surface preferably acts to tend to resist decoupling of the coupling elements from the coupled configuration.

Engagement of the engagement means is preferably effected automatically as the respective coupling elements approach the coupled configuration.

Means may be provided for selectively varying the force required to disengage the engagement formations, thereby enabling the separating force of the coupling to be varied. For example movement of the resiliently displaceable element or elements (carrying the engagement means) may be limited. This may be achieved by providing a restrictor, which may for example be a ring extending around the female connector, which ring is dimensioned to limit movement (and hence the degree of resilience) of the arm or arms.

It is preferred that the restrictor is axially moveable to vary the degree of resilience of the arm or arms. A restrictor ring may include a thread arranged to mate with a complementary thread provided on the female coupling element and /or resilient arms. When the restrictor ring is rotated relative to the body of the female coupling element displacement of the ring in the axial direction occurs. This provides that movement of the resilient arm

or arms is restricted or facilitated (effectively varying the resilience of the arm or arms) thus enabling the separating force required to decouple the coupling to be selectively varied.

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It is preferred that the coupling includes indicia means indicting the separating force at which the coupling is set to decouple. Desirably the position of the restrictor relative to the indicia means indicates the separating force at which the coupling is set to decouple. The restrictor is preferably movable adjacent the indicia. The indicia preferably indicates the position of the restrictor for the minimum separating force in order to facilitate easy, intentional, decoupling.

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Advantageously, in the coupled configuration, relative (axial) rotation is permitted between the coupling elements.

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Beneficially, seal means is provided for the coupling to inhibit egress or ingress of fluid and/or contaminants at the coupling. Preferably a seal is provided between the coupling elements. Desirably, a seal is provided between the respective coupling element and the circumferential outer surface of the respective fitted fluid line element (desirably proximate the end of the fitted fluid line element).

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In some embodiments, the respective coupling elements may be fitted to respective fluid line elements by mechanical fitment means such as screw threading, angled barbed projections, or the like. In these embodiments it is preferred that the relevant coupling element includes mechanical fitment means, which may be formed integrally with a portion of the respective coupling element.

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Desirably, the mechanical fitment means comprises one or more fitment formations provided on an inner bore of the relevant coupling element.

5 The respective fluid line may be arranged to be secured by frictional 'push fit' engagement with an inner bore of the relevant coupling element.

10 In alternative embodiments, the relevant coupling element may be bonded (for example welded) to the respective fluid line element, or manufactured integrally with the respective fluid line element.

15 In a further alternative embodiment, the relevant coupling element may be arranged to connect directly using known arrangements, for example, a screw plug end to existing drainage assemblies (for example stents, catheters and the like in common use) and to lower drainage assemblies, such as drainage bags in common use.

20 As a further alternative, the relevant coupling element may be incorporated into the open end of an existing drainage tube assembly after manufacture.

25 The coupling elements may be of any suitable material (such as polythene, nylon, polypropylene, or stainless steel).

30 It is preferred that the coupling elements comprise plastics material (preferably moulded plastics) in order to minimise the expense of the arrangement and provide disposability. Alternatively, the coupling elements may comprise more durable materials suitable for being cleaned (for example autoclaved) and reused.

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One or both of the coupling elements may be provided with valve means arranged to seal the relevant end of the respective fluid line element following decoupling. Desirably the valve means is arranged to seal the
5 respective end of the fluid line element automatically following decoupling.

One or other (or both) of the ends of respective fluid lines remote from the coupling may be provided with a
10 connector for connecting to a standard medical coupling element. Cannula's, stopcock's, locking hub's and the like.

According to a further aspect, the invention provides a
15 method of connecting medical fluid line elements comprising providing respective coupling elements fitted to respective fluid line elements, coupling the respective coupling elements in a coupling configuration permitting fluid passage through the coupling, wherein the coupling
20 is arranged to become decoupled upon a predetermined separating force acting to separate the coupling elements.

In one arrangement, a single fluid line may be cut to form separate lengths of fluid line each fitted with a
25 respective coupling element.

According to a further aspect the invention provides a method of connecting a patient medical fluid line, the method connecting fluid line as defined herein provided
30 with a coupling as defined herein.

The coupling is preferably orientated outside the body of the patient.

35 The invention will now be further described in specific

embodiments, by way of example only and with reference to the accompanying drawings in which:

5 Figure 1 is a longitudinal sectional view of a first embodiment of medical fluid line arrangement according to the invention;

10 Figure 2 is a side view of the arrangement of figure 1;

 Figure 3 is a schematic sectional view of an alternative embodiment of part of a fluid line arrangement; and,

15 Figure 4 side view of a further embodiment of medical fluid line arrangement according to the invention.

Referring to the drawings, figures 1 and 2 show a medical fluid line coupling, generally designated (101), installed in a typical medical fluid tube (1) cut transversely at (2) to form a system comprising a tube and an engineered tension sensitive coupling (101).

25 The coupling (101) consists of a male connector (3) and a female connector (4) fitted to respective cut ends of the cut tube (1). The male connector (3) is arranged to fit closely into the female connector (4) and may be secured in position by resiliently displaceable arms (5) which extend from the female connector (4) and carry
30 detent formations (15) which engage with a corresponding circumferential V groove (6) formed in the body of the male connector (3).

35 Arms (5) extend from a resilient connection with a collar portion (17) to distal ends which carry the respective

detent formations (15). The force required to displace the distal ends of arms (5) from the V groove (6) is less than that required to dislodge a typical tube installed in a patient. In this connection the inclined surface of the V groove (6) acts to cause the respective arm (5) to deform outwardly smoothly as the formation (15) rides up the inclined surface of the groove during decoupling.

In the embodiment shown in figure 4, a restrictor collar (20) may be threadably mated with female connector (4) to be axially movable along the connector. A thread (18) is provided on the female connector (4) and a complementary thread (not shown) is provided in the internal circumferential surface of restrictor collar (20). Varying the axial position of the restrictor collar (20) on the female connector (4) varies the extent to which the distal ends of arms (5) can be displaced relative to the coupling axis, and therefore varies the axial force required to dislodge detent formations (15) from engagement with the V slot (6). A scale indicia (21) is provided on the female connector (4); the position of the trailing edge of restrictor collar (20) on the scale (21) giving a conveniently readable value for the coupling separating force.

To prevent leakage of fluid from between the tube (1) and the connectors (3,4) there may be provided raised circumferential areas (7) on the inner cylindrical surfaces of the connectors. Alternatively rubber type 'O' rings of a type commonly available may be used for this purpose.

To prevent the tube (1) from pulling out of the female or male connector (3,4), teeth (8) are provided on the inside cylindrical surface of each connector arranged to point

towards the cut end of the tube. These enable the tube (1) to be readily inserted in the open end of the male and female connectors (3,4) but lock the tube (1) in place. This method of tube fixing is described by way of example only.

A depth stop (9) may be provided in both the male connector (3) and the female connector (4) to correctly position the tube within the connectors.

The circumferential V shaped slot (6) in the male connector (3) enables the female connector (4) to swivel or rotate freely on the male connector (3) thus reducing the problem of tube twist.

It is desirable to provide a circumferential seal (10) on the inside cylindrical mating surface of the female connector (4) arranged to engage with the outer cylindrical surface of the male connector (3) to prevent the loss of fluid from the junction between the male connector (3) and the female connector (4).

In figure 2, the fingers (5) on the female coupling (4) can be seen engaging with the circumferential V slot (6) on the male coupling (3).

Referring to figure 3, there is shown an alternative method of fixing the tube (1) within the male connector (3). This consists of providing a screw thread shape (1) on the internal cylindrical surface of the male connector (3). A similar screw thread shape may be incorporated as a fixing method on the female connector (4) figures 1 and 2. In this embodiment the connectors are installed by screwing onto the ends of the tube.

In use the tension sensitive coupling (101) and tube system may be utilised in a number of different ways, for example:

5 A standard drainage tube may be installed in a patient in the usual way with part of the tube fixed by any chosen method inside the body and part of the tube residing outside the body. On the portion of the drainage tube outside the body, at any convenient location before the
10 open end of the tube, the coupling (101) may be installed by transversely cutting the tube and fixing the male and female connectors to the cut ends of the tube. The male and female connectors (3,4) may then be pushed together until the detent formations (15) carried by fingers (5)
15 engage with the V slot (6).

Alternatively, if the male or female coupling connector (3,4) is placed at the open end of a tube of suitable diameter it will necessitate a further tube of suitable
20 diameter being placed on the other coupling to complete the system.

The male connector (3) would as a preference, be installed on the portion of tube nearest the patient's body since
25 the female connector (4) is inherently protected from direct contamination (by its shape) in the event of accidental decoupling when the female connector and tube may fall to the floor.

30 In the event of contamination of one or both of the male and female connectors it may be necessary to remove one or both connectors from the tube by cutting them off with a scissors, sharp knife or other suitable tool at a convenient point close to the connector and installing new
35 male and/or female connectors and/or a new portion of tube

from the coupling to the fluid receiving vessel or the like.

5 The system allows for more than one coupling (101) and tube or tube section to be installed along its length if necessary.

10 A drainage tube with a coupling (101) already installed at manufacture may be fixed inside the body with the coupling (101) residing at any position along the length of the tube outside the body. Once installed the drainage tube may be connected to a collecting bag in the usual way and the coupling (101) will, at a predetermined tension, pull apart as intended. Thus the portion of the tube inside
15 the body should remain in situ and not be subject to accidental removal.

20 A drainage tube with a coupling (101) already installed at manufacture allows for more than one coupling (101) to be installed at manufacture and/or during use when new couplings (101) and tubes may be added to the system as required.

25 It is envisaged that patients with long term drainage tubes installed may benefit from having more than one coupling along the length of the tube. This enables the drainage tube to be easily varied in length according to the patient's lifestyle situation for example, whilst ambulant or in a wheelchair the patient may prefer a short
30 tube length to the fluid receiving vessel and whilst sleeping may require a longer tube.

The system does not require skilled medical help to disconnect and reconnect the coupling and tube. The re-connection of an accidentally disconnected tube or a
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convenient length of tube may be accomplished by the patient him or herself.

Claims:

1. A medical fluid line arrangement including a coupling comprising:

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i) a first coupling element;

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ii) a second coupling element configured for releaseable engagement with the first coupling element in a coupled configuration permitting fluid communication through the coupling; and,

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iii) engagement means acting to secure the coupling elements in the coupled configuration, the respective engagement means being decoupled upon a predetermined separating force acting to separate the coupling elements.

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2. An arrangement according to claim 1, wherein the coupling elements are configured to be secured to respective upstream and downstream fluid line elements.

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3. An arrangement according to claim 1 or claim 2, wherein the separating force for separating the coupling elements from the coupled configuration is less than the force required to disassemble the coupling elements from the respective fluid line element.

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4. An arrangement according to any preceding claim,

wherein the separating force for the coupling elements is substantially in the range 5N to 25N.

5 5. An arrangement according to any preceding claim,
 wherein the separating force for the coupling
 elements is substantially in the range 5N to 15N.

 6. An arrangement according to any preceding claim
 further comprising:

10 i) an upstream medical arrangement to be fixed
 internally of a patient, the upstream
 arrangement comprising an upstream fluid line
 element; and,

 ii) a downstream medical arrangement comprising a
 downstream fluid line element.

 7. An arrangement according to any preceding claim,
20 wherein the level of the separating force of the
 coupling is variable.

 8. An arrangement according to claim 7, wherein the
 separating force can be varied manually.

25 9. An arrangement according to any preceding claim,
 wherein the first and second coupling elements
 comprise respective male and female coupling elements
 arranged to matingly engage in the coupled
30 configuration.

10. An arrangement according to any preceding claim,
wherein the first and second coupling elements
include respective axial openings arranged to be co-
aligned in the coupled configuration, permitting
5 fluid communication through the coupling.

11. An arrangement according to claim 9 or claim 10,
wherein the male connector element is provided for
the upstream fluid line element.

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12. An arrangement according to any preceding claim,
wherein the engagement means for the connector
elements include respective complementary engagement
formations engageable with one another in the coupled
15 configuration of the connector elements.

13. An arrangement according to claim 12, wherein an
engagement formation of one or other (or both) of the
coupling elements is resiliently displaceable from
engagement with the respective complementary
20 formation, permitting decoupling of the coupling
elements.

14. An arrangement according to claim 13, wherein at
least one of the engagement formations is provided on
25 a resiliently displaceable element such as an arm.

15. An arrangement according to claim 14, wherein at
least two such displaceable elements or arms are
30 provided.

16. An arrangement according to any preceding claim, wherein the first and second coupling elements comprise respective male and female coupling elements arranged to matingly engage in the coupled configuration, the female element beneficially including a collar portion and at least one arm extending from the collar portion in the axial direction.
17. An arrangement according to claim 16 including a plurality of radially spaced arms extending in the axial direction of the coupling, the arms carrying respective engagement formations for engaging one or more complementary engagement formations provided for the male coupling element.
18. An arrangement according to claim 16 or 17, wherein the or each arm preferably has a free end capable of displacement relative to the coupling axis.
19. An arrangement according to any preceding claim, wherein the engagement means comprise complementary engageable engagement formations.
20. An arrangement according to claim 19, wherein an engagement formation for at least one of the coupling elements runs circumferentially about the respective coupling element.
21. An arrangement according to claim 20 or 21, wherein at least one of the engagement formations comprises

a detent surface inclined to the axial direction of the coupling.

5 22. An arrangement according to claim 21, wherein the inclined detent surface acts to tend to resist decoupling of the coupling elements from the coupled configuration.

10 23. An arrangement according to any of claims 20 to 22, wherein engagement of the engagement means is effected automatically as the respective coupling elements approach the coupled configuration.

15 24. An arrangement according to any of claims 20 to 23, including means for selectively varying the force required to disengage the engagement formations.

20 25. An arrangement according to any preceding claim, wherein the engagement means includes one or more resiliently displaceable elements, restrictor means being provided for restricting the displacement of the displaceable element.

25 26. An arrangement according to claim 25, wherein the restrictor means comprises a ring extending around a connector element, which ring is dimensioned to limit movement of the displaceable element.

30 27. An arrangement according to claim 25 or 26, wherein the restrictor is axially moveable to vary the degree of resilience of the displaceable element.

28. An arrangement according to claim 27, wherein the restrictor comprises a ring having a thread arranged to mate with a complementary thread associated with the coupling element.
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29. An arrangement according to any preceding claim, including indicia means indicating the separating force at which the coupling is set to decouple.
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30. An arrangement according to claim 29, wherein the engagement means includes one or more resiliently displaceable elements, a restrictor being provided for restricting the displacement of the displaceable element, the position of the restrictor relative to the indicia means indicating the separating force at which the coupling is set to decouple.
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31. An arrangement according to any preceding claim, wherein, in the coupled configuration, relative rotation is permitted between the coupling elements.
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32. An arrangement according to any preceding claim, further comprising seal means inhibiting egress or ingress of fluid and/or contaminants at the coupled arrangement.
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33. An arrangement according to claim 32, wherein a seal is provided between the coupling elements.
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34. An arrangement according to claim 32 or claim 33, wherein a seal is provided between the respective

coupling element and the circumferential outer surface of the respective fitted fluid line element.

5 35. An arrangement according to any preceding claim, wherein the respective coupling elements are fitted to respective fluid line elements by mechanical fitment means.

10 36. An arrangement according to any preceding claim, wherein the first and/or second coupling element includes mechanical fitment means formed integrally with a portion of the respective coupling element.

15 37. An arrangement according to any preceding claim, wherein one or both of the coupling elements are provided with valve means arranged to seal the relevant end of the respective fluid line element following decoupling.

20 38. An arrangement according to claim 37, wherein the valve means is arranged to seal the respective end of the fluid line element automatically following decoupling.

25 39. A method of connecting medical fluid line elements comprising providing respective coupling elements fitted to respective fluid line elements, coupling the respective coupling elements in a coupling configuration permitting fluid passage through the
30 coupling, wherein the coupling is arranged to become decoupled upon a predetermined separating force

acting to separate the coupling elements.

- 5 40. A method according to claim 39, wherein a single fluid line is cut to form separate lengths of fluid line each fitted with a respective coupling element.
41. An arrangement substantially as herein described with reference to the accompanying drawings.



Application No: GB 9822381.1
Claims searched: 1-41

Examiner: Monty Siddique
Date of search: 13 October 1999

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK CI (Ed.Q): F2G (G24A1, G4J, G4K)

Int CI (Ed.6): F16L 37/28

Other: Online: WPI EPODOC JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
X	GB 2121499 A (EXXON) page 1 lines 5-8	1, 39 at least
X	GB 1482197 (F.P.T. INDUSTRIES)	1, 39 at least
X	GB 1153320 (F.P.T. INDUSTRIES)	1, 39 at least
X	EP 0569030 A1 (IVAC) entire document	1, 39 at least
X	EP 0116986 A1 (STERITECH) entire document	1, 39 at least
X	EP 0100205 A1 (RABUSHKA) page 1 lines 2-8 etc.	1, 39 at least
X	US 5820614 (BECTON) entire document	1, 39 at least
X	US 5285807 (NITZBERG) column 1 paragraph 1	1, 39 at least
X	US 4827960 (NITZBERG) column 1 lines 24-29 etc.	1, 39 at least

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.



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INVESTOR IN PEOPLE

Application No: GB 9822381.1
Claims searched: 1-41

Examiner: Monty Siddique
Date of search: 13 October 1999

Category	Identity of document and relevant passage	Relevant to claims
X	US 4465096 (ALPHA) column 1 lines 36-44 etc.	1, 39 at least

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.